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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/913,811	09/24/1997	HIROKAZU SUGIHARA	356972020100	7552

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/31/2002

36

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/913,811

Applicant(s)

SUGIHARA ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12, 14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

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***Response to Amendment***

1. The amendment filed on 8/28/02 has been entered into the record. Claim 12 has been amended. Claims 12, 14 and 16 have been withdrawn.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

***Rejections Withdrawn***

3. The terminal disclaimer filed on 8/28/02 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 6,297,025 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Therefore, the rejection of claims 12, 14 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,297,025 is withdrawn.

4. In view of amendment to the claim 12, the rejection under 35 U.S.C. 112, second paragraph is withdrawn.
5. In view of arguments, the rejection of claims 12, 14 and 16 under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al 1982 (Brain Research, 244: 382-386) is withdrawn as Yamamoto does not disclose that electrical stimulation was delivered using multiple electrodes.
6. In view of arguments and review of the application, the rejection of claims 12, 14 and 16 under 35 U.S.C. 103(a) as being unpatentable over Gahwiler et al (Neuroscience, 1982, 7; 1243-1256) in view of Sugihara et al 1995, (EPA: 689051)) is withdrawn.

***Rejections Maintained***



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7. The rejection of claims 12, 14 and 16 under 35 U.S.C. 103(a) as being unpatentable over Gahwiler et al (Neuroscience, 1982, 7; 1243-1256) in view of Gross et al. (J. of Neuroscience Methods 5: 13-22, 1982) is maintained as set forth in the previous office action.

Gahwiler et al 1982, teach a method of testing the effect of chemical substances (acetylcholine) on neuronal tissue (hippocampal sections) and measuring the electrical properties (see experimental procedures on page 1243 and 1244) before and after addition of said substances (see results and figures). Although the prior art used standard electrophysiological techniques for recording the electrical properties, the prior art specifically does not teach providing a detector comprising plurality of microelectrodes on a substrate for contacting the tissue sample (i.e., the device or apparatus).

Gross et al teach an apparatus (see material and methods/figures) for observing a physical and chemical property of a tissue or cells comprising providing photoetched electrodes integrated into the floor of a tissue culture chamber (i.e. providing a substrate with planar electrodes disposed on the same plane as the substrate) and a method for cell culturing means. (page 13). Gross et al teach recording the electrophysiological potentials with electrodes integrated into the tissue culture plate would allow the long term monitoring of neuronal activity. It would have been *prima facie* obvious to one of ordinary skill in the art at the time that the invention was made to use the apparatus designed by Gross in a method of Gahwiler et al to measure the electrical properties before and after addition of chemical substances because Gross et al suggests that the apparatus disclosed is obviously designed for long term cultures. The motivation to use this apparatus to achieve the obvious benefits is clearly suggested by Gross (see page 21, last paragraph). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the apparatus as taught by Gross et al for measuring and comparing waveforms or electrical properties of neural tissue before and after the addition of chemical substances as taught Gahwiler et al because the apparatus is designed to measure the effect of different concentrations of the chemical substances on tissue and comparing the electrical properties of long term cultures.

Applicants' arguments filed on 8/28/02 have been fully considered but they are not deemed to be persuasive.

Applicant states that Gahwiler do not measure a chronic effect (i.e., of test compound) on tissue sample and Gross does not use neural tissue sample and electropotentials for no longer than 48 hours.

It is the examiner's position that the term "chronic" is a relative term without any lower boundaries and is not defined either by the claim or by the specification. Gahwiler uses neural

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tissue and Gross suggests the apparatus disclosed is obviously designed for long-term cultures. Therefore, the teachings of prior art established a prima facie obviousness. The examiner has clearly established a prima facie obviousness using the basic criteria, suggestion and reasonable expectation of success. Gahwiler et al 1982, teach a method of testing the effect of chemical substances (acetylcholine) on neuronal tissue (hippocampal sections) and measuring the electrical properties (see experimental procedures on page 1243 and 1244) before and after addition of said substances (see results and figures). It is the examiner's position that the term "chronic" is a relative term with no lower time boundaries. Applicant cannot institute a lower bound time using a relative term. The term "chronic" is not defined by the claim; the specification does not provide a standard for ascertaining the requisite degree. Therefore, the prior art teaches a method of testing the chronic effect of compounds in a neural tissue culture. Further, Gross et al teach an apparatus (see material and methods/figures) and a method for observing a physical and chemical property of a tissue or cells comprising providing photoetched electrodes integrated into the floor of a tissue culture chamber (i.e. providing a substrate with planar electrodes disposed on the same plane as the substrate) and a method of cell culturing means. (page 13). Gross et al teach recording the electrophysiological potentials with electrodes integrated into the tissue culture plate would allow the long term monitoring of neuronal activity. It would have been prima facie obvious to one of ordinary skill in the art at the time that the invention was made to use the apparatus in a method designed by Gross to teachings of Gahwiler et al to measure the electrical properties before and after addition of chemical substances to neural tissue sample because Gross et al suggests that the apparatus disclosed is obviously designed for long term cultures. The motivation to use this apparatus and a method to achieve the obvious benefits is clearly suggested by Gross (see page 21, last

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paragraph). Thus the teachings of the prior art make the claimed invention obvious. Therefore, this rejection is maintained.

8. The rejection of claims 12, 14 and 16 under 35 U.S.C. 103(a) as being unpatentable over Gahwiler et al (Neuroscience, 1982, 7; 1243-1256) in view of Giaever et al 1993 (U.S. Patent 5,187,096) is maintained as set forth in the previous office action.

Gahwiler et al 1982 teach a method of testing the effect of chemical substances (acetylcholine) on neuronal tissue (hippocampal sections) and measuring the electrical properties (see experimental procedures on page 1243 and 1244) before and after addition of said substances (see results and figures). Although the prior art used the standard electrophysiological techniques for recording the electrical properties, the prior art specifically does not teach providing a detector comprising plurality of microelectrodes on a substrate for contacting the tissue sample (i.e., the device or apparatus).

Giaever et al teach an apparatus (see claims) for observing a physical and chemical property of a tissue or cells comprising plurality of electrodes integrated into the floor of a tissue culture chamber (i.e. providing a substrate with planar electrodes disposed on the same plane as the substrate) and cell culturing (column 2, Summary of the invention) means. Giaever et al teach by using this apparatus, the activities of cultured cells that are attached to the surfaces could be followed continuously in real time. The recording of extracellular electrophysiological potentials with electrodes integrated into the tissue culture plate would allow the long term monitoring of cell activity to changes in the physical environment and drugs (column 3 and 4). It would have been *prima facie* obvious to one of ordinary skill in the art at the time that the invention was made to use the apparatus designed by Giaever et al in a method of Gahwiler et al to measure the electrical properties before and after the addition of chemical substances because Giaever et al suggests that this apparatus is obviously designed for long term cultures. The motivation to use this apparatus to achieve the obvious benefits is clearly suggested by Giaever et al (see column 3, lines 23-55). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the apparatus as taught by Giaever et al for measuring and comparing waveforms or electrical properties of neural tissue before and after the addition of chemical substances as taught by Gahwiler et al because the apparatus designed by Giaever is for measuring the effect of different concentrations of the chemical substances on tissue and comparing the electrical properties of long term cultures.

Applicants' arguments filed on 8/28/02 have been fully considered but they are not deemed to be persuasive.

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Applicant states that Gahwiler et al do not measure a chronic effect (i.e., of test compound) on tissue sample and Giaever et al (U.S. Patent 5,187,096) do not teach method of measuring electrical properties.

It is the examiner's position that the term "chronic" is a relative term without any lower boundaries and is not defined either by the claim or by the specification. Therefore, the teachings of Gahwiler using a neural tissue for measuring the effect of compound in a method by using Giaever apparatus makes the claimed invention obvious over the prior art as explained. Therefore, the rejection is maintained.

9. The examiner would like to bring applicant's attention to M.P.E.P. §821.04 and the following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

12/17/02

  
JAMES HOUSEL 12/24/02  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600